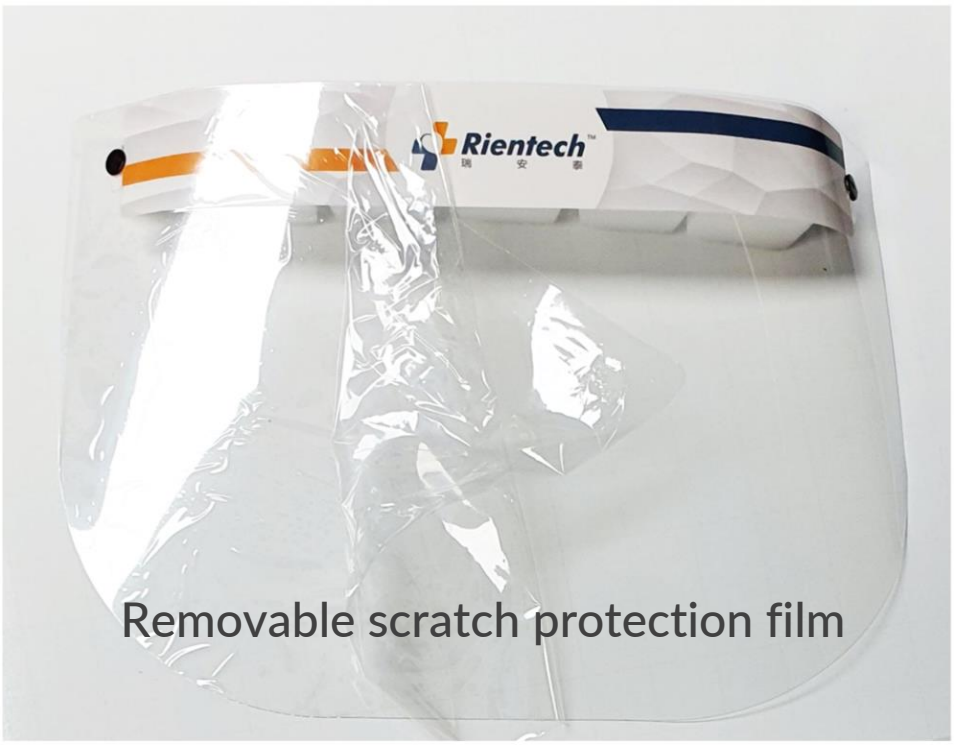
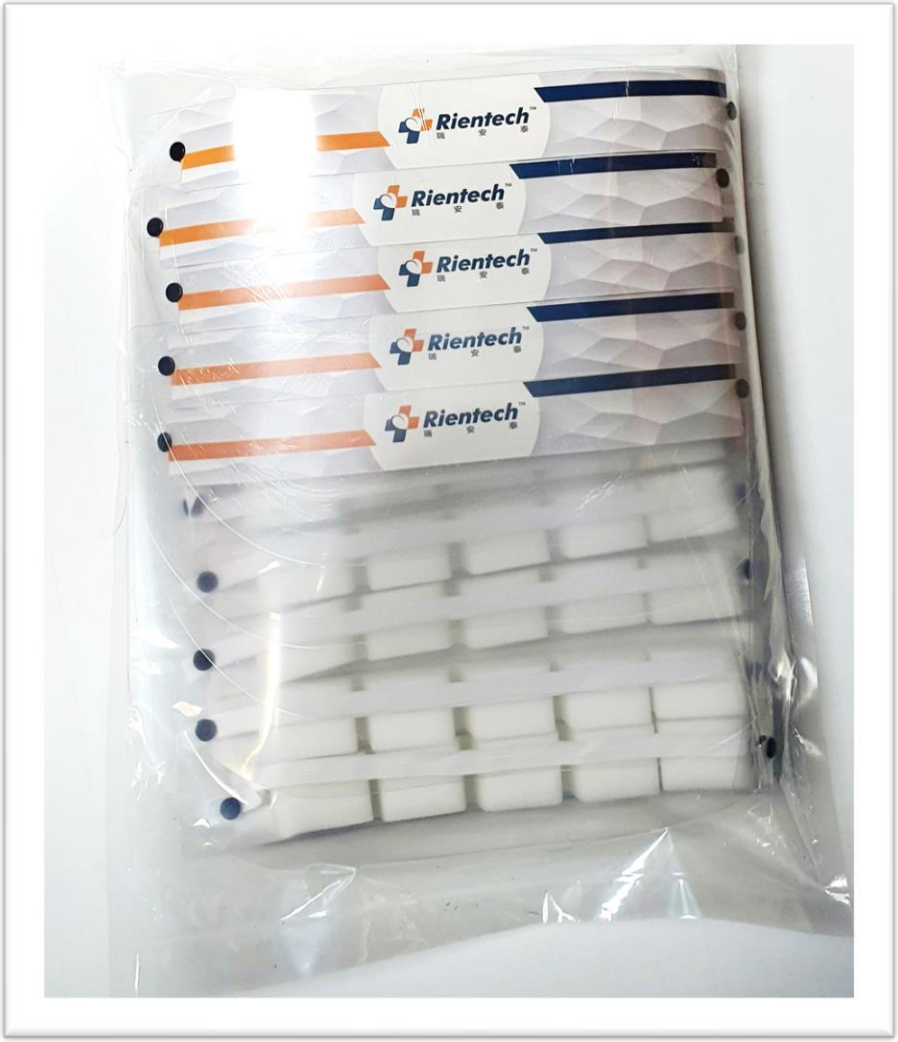
RIENTECH™ Medical Face Shield
Full Face Clear Visor

- **Anti-fog, High-transparency face shield**
- Full face protection face visor
- The medical face shield is composed of a protective polymer visor.
- Elastic head band with foam against forehead for comfort – NO LATEX.
- Designed for use in medical institutions for protection during inspection and treatment
- Protects against liquid and blood splashing.
- This product is provided non-sterile.
- FDA Approved (10063096)
- CE Certified (20202140228)
- Manufactured to ISO13485-2016, EN166:2002

www.o3group.uk



Removable scratch protection film



FDA

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Name: SHANDONG RIENTECH MEDICAL TECHNOLOGY CO., LTD.

Add: Economic Development Zone, Qihe County, Dezhou, Shandong, China

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through

The Owner/ Operator Number for this Registration is : 10063096

Listing No	Code	Device Name
D375314	OEA	Isolation Gown, Protective Clothing
D375316	BYG	Medical Face Shield,
D375313	HOY	Medical Safety Goggles
D375312	KEA	Disposable Medical Surgical Mask

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate - holder' s device or establishment by the U.S Food and Drug Administration.

ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification: Mar. 17, 2020

Date of expiration: Dec. 31, 2020

SH OFFICE

TEL:0086-21-50313932 Boyle Wang Phone:0086-18930777676 info@truthful.com.cn

ABMED SERVICE INC.

36 Soyth 18th Avenue, Suite A Brighton,CO USA 80601

TEL:213-375-3998 FAX:213-375-3998 info@abmed.com.cn

REGISTRATION NO. 04717Q10000266

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Shandong Rientech Medical Technology Co., Ltd.

Registered Address: Brandeis Industrial Park, Qihe Economic &, Development Zone, 251100 Qihe, Shandong Province, P.R. China

Manufacturing Address: Brandeis Industrial Park, Qihe Economic &, Development Zone, 251100 Qihe, Shandong Province, P.R. China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

Design, Development, Production and Service of Sirolimus-eluting Coronary Stent System,Medic al Face Shield, Medical Safety Goggles.

Date of issue: July 14,2017

Date of expiry: July 13,2020

Date of change: March 23,2020

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER:
NAME: **SHANDONG RIENTECH MEDICAL TECH CO., LTD**
ADDRESS: BRANDEN INDUSTRIAL PARK, QIHE ECONOMIC& DEVELOPMENT ZONE, 251100, SHANDONG PROVINCE, CHINA,
TEL.: +86-534-5676662 FAX: +86-534-5677386
E-MAIL: CEO@BRANDENTECH.COM

MEDICAL DEVICES:

NAME OF DEVICES	*TYPE(S) AND BATCH QUANTITY*	LOT No.
Medical Face Shield	*L32 , 200,000 PCS*	20200402

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY

EC REP

EUROPEAN REPRESENTATIVE:
CORDIMAX DEUTSCHLAND GMBH
C/O SONNENBERG SERVICES GMBH STERNSTR.67,
40479 DUESSELDORF
TEL: +4915129909065; FAX: +49(211)51369278

DATE OF DECLARATION: 2020.4.02

SIGNATURE:

NAME: HAIJUN ZHANG
POSITION: CEO OF THE MANUFACTURER

PRODUCT TEST REPORT OF

SHANDONG RIENTECH MEDICAL TECHNOLOGY CO., LTD.

Product Name			Medical Face Shield	Tested Department	Production department	
Product Model			L32	Test basis	Technical requirements for Medical face shield	
Product Batch Number			20200402	Sampling Mode	Random sampling	
Product Quantity			200,000 PCS	Sampling Date	20200402	
Sampling Quantity			8 PCS	Testing Date	20200402	
NO	Test Item(s)		Test Requested	Test Results	Conclusion	Remarks
1	size	L1	32.0±1.5cm	31.7-32.2cm	Qualified	\
		L2	22.0±1.5cm	21.8-22.3cm	Qualified	\
		L3	32.0±1.5cm	31.7-32.2cm	Qualified	\
		L4	28.0±1.5cm	27.8-28.3cm	Qualified	\
2	Appearance		Medical Face Shield shall be free from projections, sharp edges or other features which could cause discomfort.	Meet the requirements	Qualified	\
Conclusion(s): The tested products meet the technical requirements of medical face shield.						

Inspector: Cong Cong Liu Auditor: Anyun Approved: Wenying Huo